



IN THE
UNITED STATES
PATENT AND TRADEMARK
OFFICE

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| <i>Application No.</i> | 08/826,361 |
| <i>Filing Date</i> | 26 March 1997 |
| <i>First Named Inventor</i> | Sietse MOSSELMAN |
| <i>Group Art Unit</i> | 1646 |
| <i>Examiner Name</i> | M.D. Pak |
| <i>Attorney Docket No.</i> | 2355-124 |

Title of the Invention: NOVEL ESTROGEN RECEPTOR

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

JUN 04 2003

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TECH CENTER 1600/2900

Dear Sir:

Further to the Request for Continued Examination (RCE) filed on 5 May 2003, Applicants have discovered that the Supplemental Information Disclosure Statement and the Information Disclosure Statement By Applicant filed with the RCE contained an incorrect Serial Number. Accordingly, copies of the publications and other documents cited and discussed therein are being resubmitted as part of this Second Supplemental Information Disclosure Statement along with two additional documents not included in the Supplemental Information Disclosure Statement in order to ensure that the publications and other documents are considered.

Under the provisions of 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant submits herewith copies of publications and other documents that the Office may wish to consider in examination of the subject application. The publications are listed on the attached form entitled "Information Disclosure Statement by Applicant." These publications and documents were cited in an opposition filed with respect to the corresponding granted European patent, EP 0 798 378 B1.

With respect to these references, as is clear from the titles and/or abstracts, Koike et al. relates to rat estrogen receptor cDNA (not the human receptor), Lees et al. relates to mouse estrogen receptor (not the human receptor), Giguere et al. relates to a receptor for the morphogen retinoic acid (a totally different receptor), Enmark et al. relates to a new rat orphan receptor Rev-ErbA β (not the human receptor), and Kuiper et al. (1996) relates to rat estrogen receptor (not the human receptor).

Hence, all of these references do not relate to the human estrogen receptor β , which is the subject of the present application.

Parker is a report of a meeting that took place on 17-23 March 1996, i.e. before the earliest priority date of the present application. Parker describes that there is a second estrogen receptor called ER β , disclosed in a lecture by Kuipers (presumably Kuiper) and Gustafsson. No details regarding, for example, ER β 's amino acid or nucleotide sequence, are disclosed in Parker.

The handwritten notes of Dr. Gustafsson's presentation were made by an undisclosed person during the lecture. These notes also do not give any detail regarding amino acid or nucleotide sequence. A typed version of these handwritten notes is also provided as submitted with a letter from D Young & Co. dated 8 April 2003 in an opposition proceeding for EP 0 792 292 B1. The letter from Withers & Rogers dated 16 May 2003 on behalf of Karo Bio in this same opposition states that the human form of ER β could not have been disclosed at the Lake Tahoe meeting because it had not been isolated at that date. Applicants have advised the undersigned that at the oral proceedings for this opposition, the Opposition Division of the EPO declared the handwritten notes constituted an incredible account by an undisclosed person which did not provide any sequence information and therefore was not allowed as prior art.

Kario Bio AB (Kuiper et al.; EP 0792292) corresponds to WO 97/09348, cited in the original Information Disclosure Statement.

Mosselman et al. discloses subject matter, i.e., a human ER β identified as X99101, that is described in the first priority document to which the present application is entitled. In particular, Mosselman et al. discloses the amino acid sequence of X99101, which is identical to SEQ ID NO:5 set forth in claim 4 of the present application. The amino acid sequences of SEQ ID NO:5, SEQ ID NO:6, and SEQ ID NO:21 are entitled to the priority date of 26 March 1996, a date prior to Mosselman et al. The full-length amino acid sequence, i.e., SEQ ID NO:25, is entitled to the priority

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date of 22 November 1996. There is no teaching or suggestion in Mosselman et al. for a person of ordinary skill in the art to arrive at the full length sequence of the human estrogen receptor β .

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| RESPECTFULLY SUBMITTED, | | | | | |
| Name and Reg. No. | Jeffrey L. Ihnen, Registration No. 28,957 | | | | |
| Signature |  | | | Date | 30 May 2003 |
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| City | Washington | State | D.C. | Zip Code | 20005 |
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code.

For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴**Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.** ⁵**"Applicant is to place a check mark here if English language translation is attached. AB indicates that only an English language abstract is attached.**

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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT  | | | | Complete if Known | |
| | | | | Application Number | 08/826,361 |
| | | | | Filing Date | 26 March 1997 |
| | | | | First Named Inventor | Sietse MOSSELMAN |
| | | | | Group Art Unit | 1646 |
| Examiner Name | M.D. Pak | | | | |
| Sheet | 2 | of | 2 | Attorney Docket Number | JUN 04 2003 TECH CENTER 1600/2900 2355-126 |

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| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | | | |
|---|-----------------------|--|--|-----------------|--|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | | | |
| | 2 | KOIKE, S. et al., "Molecular cloning and characterization of rat estrogen receptor cDNA," <i>Nucleic Acids Res</i> 15:2499-2513 (1987). T² | | | |
| | 3 | LEES, J.A. et al., "Identification of two transactivation domains in the mouse oestrogen receptor," <i>Nucleic Acids Res</i> 17:5477-5488 (1989). | | | |
| | 4 | GIGUERE, V. et al., "Identification of a receptor for the morphogen retinoic acid," <i>Nature</i> 330:624-629 (1987). | | | |
| | 5 | ENMARK, E. et al., "Identification of a novel member of the nuclear receptor superfamily which is closely related to Rev-ErbA," <i>Biochem Biophys Res Comm</i> 204:49-56 (1994). | | | |
| | 6 | MOSSELMAN, S. et al., "Erβ: identification and characterization of a novel human estrogen receptor," <i>FEBS Letters</i> 392:49-53 (1996). | | | |
| | 7 | KUIPER, G.G.J.M. et al., "Cloning of a novel estrogen receptor expressed in rat prostate and ovary," <i>Proc Natl Acad Sci USA</i> 93:5925-5930 (1996). | | | |
| | 8 | PARKER, M.G., "Nuclear receptor superfamily reunion," <i>TIG</i> 12:277-278 (1996). | | | |
| | 9 | Handwritten notes of Dr. Gustafsson's presentation at Keystone Symposium Nuclear Receptor Superfamily, Lake Tahoe, CA, 22 March 1996 (meeting report in Parker, <i>supra</i>) taken by attendee and submitted in opposition of corresponding European patent (3 pgs). | | | |
| | 10 | Typed version of handwritten notes of 9, <i>supra</i> , and letter from D. Young & Co. dated 8 April 2003 submitting this typed version in opposition to EP 0 792 292 B1. | | | |
| | 11 | Letter from Withers & Rogers dated 16 May 2003 submitted in opposition to EP 0 792 292 B1 on behalf of patentee. | | | |
| Examiner Signature | | | | Date Considered | |

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